Janet Moore, *Star Tribune*

Minnesota's senators and congressmen want a say in any FDA device-approval changes.

Eight bipartisan members of Minnesota's congressional delegation are raising concern about proposed changes in the way most medical devices are cleared for use in patients.

The group said in a letter to Food and Drug Administration Commissioner Margaret Hamburg that any changes to the agency's 510(k) approval process "should not be made unless there is clear evidence that the changes are necessary to address a demonstrated public health concern."

The FDA is contemplating vast changes to the 510(k) approval pathway that would presumably toughen regulations for companies seeking to launch their products in the United States. Currently, these firms need to prove their product is substantially similar to one already on the market -- often without clinical studies on patients.

Minnesota's formidable medical technology industry -- with help from local members of Congress -- has loudly protested some of the changes, saying excessive regulation will stifle the development of new and innovative products, as well as quash the creation of lucrative jobs that propel the state's economy.

The Nov. 24 letter was signed by Democratic senators Amy Klobuchar and Al Franken, Republican Reps. Erik Paulsen, John Kline and Michele Bachmann, as well as Democratic Reps. Betty McCollum, Keith Ellison and Collin Peterson. Many of the same bipartisan players rallied earlier this year to cut in half a proposed $40 billion tax on medical device companies that was designed to help pay for health care reform.

The letter calls med-tech "one of the few sustained bright spots in our economy over the last five years." It points out that Minnesota, home to more than 500 medical device firms employing almost 35,000 people, has a med-tech industry that "is active and continually growing."

The letter encourages Hamburg, an Obama appointee, to work with the delegation in coming months as changes are contemplated to the 510(k) process. "This industry is so important and vital to the state as a job provider and a source of innovation," said Paulsen, who serves as co-chair of the House Medical Technology Caucus. "We need to ensure that this industry remains a success story in Minnesota."

An FDA spokesman could not be reached for comment on the letter Monday; Paulsen said the delegation has not received a response.

The FDA is expected to release more information on impending changes in January. And next year, the prestigious Institute of Medicine will release a report on the process. The institute's review was launched by FDA leaders after consumer groups complained that medical devices were being cleared without proper vetting.